REMARKS

Status of Claims

Claims 1, 3-11, 14-16, 19, 21-24, 31, 32 and 34-37 are pending. Pursuant to an election of species requirement, claims 3-6, 21, 22 and 31-37 have been withdrawn from consideration. Claims 1 and 31 have been amended as shown above. Thus, claims 1, 3-11, 14-16, 19, 21-24, 31, 32 and 34-37 are pending as shown above.

Election of Species Requirement

The election of species requirement has been made FINAL.

Applicants again note that they traversed on the grounds that it would not be unduly burdensome to search all allegedly distinct species together. Thus, contrary to the Examiner's statement, the traversal was not made on the grounds that a search would necessarily reveal art related to the other groups if the search was being done *de novo,* but rather that it would not be unduly burdensome to search all species together because **a search for all allegedly distinct species has already been conducted**. Not only has the search already been conducted and the relevant references found, for example with regard to cytokines, these references have also been applied previously and, moreover, are applied again in this Office Action. *See,* § 102(e) below.

Applicants also reiterate that it is to be understood that the election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to the additional species.

35 U.S.C. § 102(e)

Claims 1, 11, 14 and 19 remain rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,231,590 (hereinafter "Slaikeu"). Slaikeu is cited for allegedly disclosing a vaso-occlusive composition consisting of a coil and a bioactive material that comprises at least one cytokine such as PDGF, bFGF, VEGF and TGF-beta. (Office Action, paragraph 3). In response to Applicants' previous response, the Office Action states:

> Applicant argues that Slaikeu '590 must have both an inner and an outer layer and therefore cannot meet the closed transition language of "consisting of." Applicant points to column 3 lines 12-15 to point out there may be more than one layer on the base member. However, Slaikeu states that the inner layer is ***optional*** (Column 3 lines 11-12). The device does not have to have both an inner and outer layer. The rejection over Slaikeu is proper. (Office Action, paragraph 9, emphasis in original).

Applicants agree that the inner layer of Slaikeu is optional. However, the salient issue remains that the closed transition language of pending claims 1, 11, 14 and 19 necessarily excludes devices including both an inner and outer coating, and, in addition, excludes devices in which a single coating includes additional components to those set forth in the Markush group of claim 1. Slaikeu unambiguously teaches that any bioactive materials (*e.g.,* cytokines) are added into the outer **collagenous** layer. *See, e.g.,* column 7, lines 7-21, stating "the outer collagenous or proteinaceous coating may further contain additional materials which have one or more functions..."

Therefore, the fact that Slaikeu's outer coating may contain a cytokine is utterly irrelevant to the question at hand. What is relevant to determining patentability of the pending claims is the fact that Slaikeu requires the presence of a collagenous material in addition to the cytokine, while the claimed subject matter does not include such collagenous materials. Accordingly, the claimed compositions and methods always include fewer elements than contained in Slaikeu and, as such, Slaikeu cannot anticipate any of the pending claims.

35 U.S.C. § 102(b)

Claims 1, 7, 15, 19 and 24 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,891,192 (hereinafter " Murayama"). (Office Action, paragraph 4). Murayama is alleged to disclose a vaso-occlusive coil coated with a thrombus-stabilizing molecule. Office Action, paragraph 4, citing column 1, lines 60-62 and column 2, line 62 to column 3, line 8 of Murayama.

Applicants again note that the thrombus-stabilizing molecules recited in claims 1, 7, 15, 19 and 24 are defined in the specification as molecules which stabilize thrombus formation and/or inhibition of clot lysis. *See, e.g.,* page 7, lines 13-14 of the specification. Thus, "thrombus-stabilizing molecules" are specifically defined and Murayama fails to teach or disclose molecules as claimed. Indeed, in column 1, lines 60-62, Murayama states that the "improved ability of these novel ion-implanted, protein-coated implants to control thrombosis ... ." Similarly, at col. 2, line 64 to col. 3, line 8, Murayama states that "cell adhesion proteins" such as collagen, fibronectin, vitronectin, laminin or fibrinogen may be used for coating. There is absolutely nothing in these passages relating to thrombus-stabilizing molecules as set forth in claims 1, 7, 15, 19 and 24. The fact that the implant may "control thrombosis" says nothing about thrombus-stabilization. Nor are the cell adhesion proteins taught at column 2, line 64 through column 3, line 8 considered thrombus-stabilizing molecules, as claimed.

Therefore, because Murayama does not teach or suggest thrombus-stabilizing molecules,

this reference cannot anticipate any of the pending claims.

35 U.S.C. § 103

The Examiner has also invoked two new obviousness rejections. First, claims 1, 7, 8, 9, 10, 23 and 24 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,690,666 (hereinafter "Berenstein") in view of U.S. Patent No. 4,414,976 (hereinafter "Schwarz"). (Office Action, paragraph 6). In addition, claim 16 is newly rejected as allegedly obvious over Slaikeu in view of U.S. Patent No. 6,256,979 (hereinafter "Nikolchev"). (Office Action, paragraph 7).

Applicant addresses the rejections in turn.

Berenstein

Claims 1, 7, 8, 9, 10, 23 and 24 were as allegedly obvious over Berenstein in view Schwarz. (Office Action, paragraph 6). Berenstein is cited for allegedly disclosing a vaso-occlusive coil that is used with a tissue adhesive while Schwarz is cited for teaching that a surgical tissue adhesive can be made with Factor XIII, plasminogen activator or plasmin inhibitor in order to stimulate wound healing. *Id.* It is alleged that it would have been obvious to provide the device of Berenstein with the tissue adhesive of Schwarz in order to promote wound healing. *Id.*

Applicants again note that Berenstein does not relate to devices as claimed that consist of a vaso-occlusive member and a bioactive material. Instead, Berenstein teaches an ultrasoft coil which may be used as a "**substrate** to localize the **subsequent** infusion of tissue adhesives..." *See,* col. 3, lines 18-29 of Berenstein, emphasis added. In other words, the pending claims are directed to devices that include, upon construction, both a vaso-occlusive member and a bioactive component. The bioactive component is not subsequently infused as described in Berenstein's devices, but a component of the device. Thus, the Examiner's reliance this passage of Berenstein as allegedly providing the motivation to combine this reference with Schwarz (or any other reference teaching thrombus-stabilizing molecules) is entirely misplaced. There is absolutely no teaching or suggestion in Berenstein regarding either the nature of the tissue adhesive or that the material is attached to the coil in any way. Rather, Berenstein teaches that any additional component is infused into the vessel after deployment of the ultrasoft coil. Simply put, Berenstein does not teach or suggest the elements of the pending claims and does not provide the motivation to combine its disclosure with Schwarz's.

Schwarz fails to provide what is missing from Berenstein. Schwarz is also completely silent as to vaso-occlusive members set forth in pending claims. Furthermore, as noted above, Berenstein's disclosure of subsequent infusion of tissue adhesives would not have lead one to combine disclosures with Schwarz. The reverse is also true as there is no motivation in Schwarz to combine its disclosure with Berenstein. Furthermore, even if the disclosures were to be combined, such a combination would not lead to the claimed subject matter because there is no suggestion in either reference that the thrombus-stabilizing molecule is a component of the vaso-occlusive member, as claimed.

Accordingly, Applicant requests that this rejection be withdrawn.

Slaikeu

Claim 16 was allegedly obvious over Slaikeu in view Nikolchev. (Office Action, paragraph 7). Slaikeu is cited as above for allegedly disclosing the claimed invention except for the vaso-occlusive member being micro-textured. *Id.* Nikolchev is cited for disclosing micro-texturing in order to promote tissue ingrowth and enhance the occlusion of a vessel. *Id.*

Applicant submits, for the reasons detailed above, that Slaikeu fails entirely to disclose compositions or methods, as presently claimed. For its part, Nikolchev also fails to teach vaso-occlusive members as claimed. Therefore, Slaikeu, alone or in combination with Nikolchev, cannot render pending claim 16 obvious.

CONCLUSION

In view of the foregoing remarks, Applicant believes the claims are in condition for allowance and requests early notification to that effect. If the Examiner believes there are any outstanding issues, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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